



May 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Irradiation in the Production, Processing, and Handling of Food**
Advanced Notice of Proposed Rulemaking
Docket No. 98N-1038
64 Fed.Reg. 7834 (February 17, 1999)

AARP appreciates this opportunity to comment on the Food and Drug Administration's (FDA) advance notice of proposed rulemaking (ANPR) concerning the labeling of irradiated foods. AARP is very concerned about the safety of the food supply because older persons are particularly susceptible to illnesses from foodborne contamination.¹ Unless effective measures are taken to reduce it, the number of deaths and illnesses from microbial contamination in food will increase as the number of elderly increases.²

It is clear that irradiation can play a role in improving the safety of the food supply.³ But AARP also believes that consumers have a right to know whether the food they are purchasing has been irradiated. People who are at an increased risk of developing foodborne illnesses (e.g., children and older persons) may want to purchase products that have been treated with irradiation. At the same time, however, there are many people who want to avoid irradiated products for various reasons, including the impact of irradiation on the environment and worker safety. Since there is no way to tell from the product itself whether or not it has been irradiated, a disclosure statement on the product label is absolutely necessary.

In previous rulemakings, FDA has determined that labeling of irradiated foods was necessary because such processing is a material fact that must be disclosed to the consumer to prevent deception. We are aware of no evidence or other information to support altering this determination.

¹ Institute of Medicine, National Research Council, *Ensuring Safe Food: From Production to Consumption* 56 (1998).

² *Id.* From 1965 to 1995, the number of Americans aged 65 or older grew by 82 percent. According to the U.S. Census Bureau, the U.S. can expect one-fifth of the population to be over the age of 65 within the next three decades (U.S. Census Bureau, Data base news in aging. *Federal Interagency Forum on Age-Related Statistics* (1997)).

³ While this ANPR addressed only labeling issues, we do want to take this opportunity to note our position that, because of concerns about its safe use, irradiation should be considered only when other less costly and less controversial treatments prove ineffective. We also want to encourage FDA to require that plants using irradiation conduct microbial testing immediately prior to the irradiation step in order to ensure that products that are to be irradiated do not exceed the levels at which the irradiation process has been demonstrated to work.



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A recent telephone survey on irradiation labeling, commissioned by AARP and the Center for Science in the Public Interest (CSPI)⁴ found:

- Overwhelming support (88.6 percent) in favor of labeling of irradiated foods to indicate that they have been irradiated;
- Strong support for placement of the irradiation label on the front of the food package (59.1 percent in favor); and
- Strong support for use of the labeling term “Treated by Irradiation” (57.8 percent in favor) instead of the alternative terms “Electronically Pasteurized” (15.3 percent in favor) or “Cold Pasteurized” (9.2 percent in favor).

In light of these findings, the existing labeling requirements for irradiated food products should not be changed unless and until such change is supported by verifiable research and consumer preference data. AARP believes that FDA should continue to require that the labels of irradiated foods contain both the radura symbol and a verbal disclosure statement, and should continue to require use of the term “irradiation” and not “electronic” or “cold pasteurization.” These latter terms, while technically synonymous with irradiation, are generally unfamiliar to consumers.

In order to be effective, an irradiation disclosure statement must be prominent and conspicuous from the perspective of all consumers, especially those with impaired vision.⁵ (Those with impaired vision are disproportionately older Americans, one of the subpopulations most susceptible to foodborne illnesses.) Consistent with the findings of the 1999 Irradiation Survey, the disclosure statement should appear on the principal display panel of the food package near the product name, and should not be lost among the other text on the display panel. It must also be printed in a sufficiently large type size and clear style.

The Food and Drug Administration Modernization Act (FDAMA) limits the agency’s ability to require that the irradiation disclosure statement be printed in an optimal type size for older Americans. There is widespread agreement among readability experts that 12-point type is the best type size for older persons. However, FDAMA prohibits the agency from requiring that the disclosure statement be any more prominent than the declaration of ingredients (which must be printed in type no smaller than 1/16th inch -- or approximately 6-point type). We are very concerned that irradiation disclosure statements printed in 6-point type will be unreadable for many older Americans. We urge FDA to consider ways (other than larger type size) to make the disclosure statement more readable (e.g., requiring that the statement be placed in a box, or that it be printed in a contrasting color of ink).

⁴ Bruskin/Goldring Research, *Irradiation Telephone Survey for the CSPI and AARP* (April 16-18, 1999) [hereinafter cited as 1999 Irradiation Survey]. The questions asked in the poll and the summary of its findings are attached as Appendix A to CSPI’s comments.

⁵ Over 60 percent of those considered visually impaired are older persons. By age 65, virtually every person will suffer some loss of ability to focus, to resolve images, to discern colors, and to adapt to light. AARP, *Truth in Aging: Guidelines for Accurate Communication* 25 (1986).

AARP believes that all irradiated ingredients listed in multiple-ingredient products be accompanied by the phrase "irradiated" or "treated by irradiation." It is just as misleading to fail to disclose the fact that an ingredient is irradiated as it is to fail to note that a single-ingredient food has been treated by irradiation. In fact, we believe that FDA should require that any multiple-ingredient product bear the prescribed radiation disclosure statement if an irradiated ingredient constitutes more than 40 percent of the overall product by weight. This disclosure is necessary to eliminate any misleading impression that the food has not been irradiated.

While the ANPR does not address use of "incentive labeling," we would like to address this issue in these comments. FSIS currently allows statements such as "treated by irradiation to reduce salmonella and other pathogens" under the irradiation labeling provisions for poultry products, provided such labels are not false or misleading. AARP agrees that statements such as those already permitted for poultry products are appropriate, but only if certain stringent requirements are met.

The Association urges FDA to define a minimum amount of pathogen reduction that must be achieved to allow companies to use a pathogen-reduction label. Moreover, the agency should require that the company seeking approval for such a labeling statement provide the agency with documentation demonstrating that its processing methods are achieving the requisite reduction in the specified pathogen. In addition, the company should be required to conduct, on a routine basis, microbial testing of the product immediately prior to the irradiation step, to show that pathogen levels are not too high, and to routinely verify through microbial testing that the irradiation process is continuing to eliminate or reduce the levels of the pathogen in question, to the degree required.

Implementation and strict enforcement of the foregoing measures are crucial to consumer acceptance of the proposed incentive labeling scheme. A label indicating that a product has been irradiated to reduce foodborne-illness-causing pathogens would be misleading to consumers if the irradiation process did not reliably achieve a significant degree of pathogen reduction.

AARP opposes any type of incentive labeling that would allow companies to label their products as being completely free of a particular pathogen or pathogens. Such labels would be potentially misleading because they would give consumers a false sense of security, particularly in instances when post-irradiation recontamination occurs before the product reaches consumers. Such labeling could also reduce the level of care consumers use in handling and cooking products that have been irradiated, increasing the potential for cross-contamination.

AARP appreciates this opportunity to comment on this ANPR on irradiation labeling. Please contact Larry White of our Federal Affairs Department at 202-434-3800 should you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin A. Corry", with a long, sweeping horizontal line extending to the right.

Martin A. Corry
Director
Federal Affairs